UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRIAN VICENTE, **Plaintiff,** **v.** **DEPUY SYNTHES COMPANIES, et al.,** **Defendants.**	Civ. No. 20-1584 (KM) (JBC) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

This matter comes before the Court on the motion of Defendants DePuy Synthes Companies and DePuy Synthes Sales, Inc. (DE 19)[1] to dismiss Plaintiff Brian Vicente's Second Amended Complaint (DE 18) pursuant to Federal Rule of Civil Procedure 12(b)(6). The action arises from personal injuries that Vicente sustained due to allegedly defective medical devices manufactured, designed, and distributed by Defendants. Vicente asserts claims under the New Jersey Products Liability Act ("NJPLA"), N.J. Stat. Ann. § 2A:58-C *et seq.*, for design defect, manufacturing defect, and inadequate warnings. Vicente also asserts a common-law claim for breach of express and implied warranty.

[1] Citations to the record will be abbreviated as follows. Citations to page numbers refer to the page numbers assigned through the Electronic Court Filing system, unless otherwise indicated:

"DE" = Docket entry number in this case.

"Compl." = Plaintiff's initial Complaint filed in state court (DE 1-1)

"Am. Compl." = Plaintiff's First Amended Complaint and Jury Demand (DE 5)

"2AC" = Plaintiff's Second Amended Complaint and Jury Demand (DE 18) (The "complaint," unless otherwise specified, refers to this document.)

I. Summary

A. Factual Background[2]

The factual allegations of the Second Amended Complaint are accepted as true for purposes of this motion. Defendants are the manufacturers, marketers, and distributors of the LC-DCP SYSTEM (the "System") plates and screws.[3] These screws and plates are "often utilized in surgical procedures involving the knee or leg, among other things." (2AC ¶8.)

On July 17, 2015, Vicente was involved in a motorcycle accident resulting in fractures to his left femur, left metatarsal, and toes. (2AC ¶22.) Consequently, on July 30, 2015, Vicente underwent open reduction with internal fixation ("ORIF") procedures at University Hospital. (2AC ¶23.) Vicente alleges that the Defendants' screws and plates were used during this procedure. (2AC ¶24.)

Vicente underwent several additional procedures "related to open wound conditions and debridement," also using the Defendants' plates and screws. (2AC ¶25.) During these supplementary procedures, occurring on March 3, 2015, August 3, 2015, January 1, 2016, and March 1, 2017, various issues of hardware failure involving Defendants' devices were reported. (2AC ¶¶ 25-32.)

The Second Amended Complaint identifies specific devices manufactured by Defendants that were used in Vicente's procedures occurring on July 30, 2015, August 3, 2015, and March 1, 2017. (2AC ¶¶ 36, 63, and 76.) For each of these specific devices, the complaint provides anecdotal reports of these devices (1) undergoing hardware failure; (2) causing adverse reactions in various patients; or (3) being the subject of product recalls. (2AC ¶¶ 36-81.) The Second Amended Complaint also alleges that the Federal Drug Administration ("FDA"), through its Medical Product Safety Network, issued numerous adverse reports concerning alleged hardware failure involving

---

[2] A more detailed factual background can be found in my prior opinion. (*See* DE 11.)

[3] "The LC-DCP SYSTEM stands for the defendants' 'Limited Contact Dynamic Compression Plate." (2AC ¶¶8-9.)

Defendants' Devices, resulting in injuries to patients (2AC ¶¶ 82-87.) The complaint also identifies various product measures taken by the FDA after inspection of the Defendants' Pennsylvania facility. (2AC ¶88.)

According to Vicente, the Defendants promoted the System as (1) "a safe device for stabilization of the knee or leg, subsequent to a surgical procedure in which it was utilized"; and (2) "technically sound and safe and, through publication, touted its technical improvements." (2AC ¶¶10-11.) Further, Defendants "touted" numerous features of the system, including:

- Improvements made in the plate component of the system.
- The system's contouring that contributed to satisfactory reduction and adequate stability.
- The system's design, which ensured uniform rigidity, hence a continuous curvature after bending.
- The use of a lag screw, which achieved 'full compression' or actually 'optimum compression,' in that it slid freely through the gliding hole.
- The fact that the system was fit for all applications, and that due to its spring mechanism, all types of applications were possible.
- The soundness of other components of the system," such as the buttress plate, the neutralization plate, and the protecting plate.

(2AC ¶¶12-17.)

Vicente alleges that Defendants placed the System "into the stream of commerce with the actual or imputed knowledge that the said product was defectively designed and/or manufactured; that it was likely to fail after its insertion in surgical procedures; and that the said product was not fit for its intended use or uses." (2AC ¶18.) Specifically, the Defendants "knew or had reason to believe of the propensity for the [System] to fail since it was based on technology co-opted by [Defendants] that often failed in the past." (2AC ¶19.) Despite this knowledge, Vicente claims, the Defendants "continued to manufacture [the System] with the same defective design." (2AC ¶21.)

The Second Amended Complaint asserts four claims against the Defendants:

- Count One: Strict Liability – Design Defect
- Count Two: Strict Liability – Manufacturing Defect
- Count Three: Strict Liability – Inadequate Warning
- Count Four: Breach of Express and Implied Warranty.

(2AC ¶¶89-113.)

The allegations in the Second Amended Complaint are the same as in the First Amended Complaint, with the exception that Vicente now argues that multiple devices manufactured by the Defendants resulted in his injuries. (*Compare* 2AC ¶¶89-113 *with* Am. Compl. ¶¶36-60.) Defendants move to dismiss the Second Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. (DE 19-1.)

B. Procedural History

On November 27, 2019, Vicente filed this action in the Superior Court of New Jersey Law Division, Essex County against Johnson & Johnson, DePuy Synthes, University Hospital, Rutgers University, and Mark Adams, MD. DePuy Synthes Sales, Inc., ("DePuy") (inaccurately named as Depuy Synthes), removed the matter to the United States District Court for the District of New Jersey pursuant to 28 U.S.C. §§ 1332(a), 1441(a), and 1446 based on this Court's diversity jurisdiction. (DE 1 at 1-2.)

Vicente is a citizen of New Jersey. (Compl. ¶1.) On January 14, 2020, Vicente filed a voluntary dismissal of his claims against University Hospital, Rutgers University, and Mark Adams, M.D., all who were alleged to be New Jersey citizens. (Compl. ¶¶4-6; DE 1-4 at 2.). A month later, Plaintiff filed a voluntary dismissal of Johnson & Johnson, also alleged to be a citizen of New Jersey (Compl. ¶2; DE 1-5 at 2), leaving DePuy as the only defendant remaining.

On February 13, 2020, in its Notice of Removal (DE 1), Depuy submitted that its principal place of business is in Massachusetts, not Pennsylvania. (DE

1 ¶13.) Accordingly, based on complete diversity of citizenship between the parties, DePuy removed the matter to this Court. (DE 1.)

Vicente filed the First Amended Complaint (DE 5) on March 5, 2020, naming DePuy and DePuy Synthes Companies as defendants. Two weeks later, Defendants moved to dismiss the First Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. (DE 6.) On May 21, 2021, Vicente filed his opposition (DE 7) and on June 8, 2021, Defendants filed their reply brief. (DE 9.)

By order dated December 21, 2020, I granted Defendants' motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). (DE 12.) This dismissal was entered without prejudice to the filing, within 30 days, of a proposed Second Amended Complaint. (DE 12.)

On January 27, 2021, Vicente filed a motion for an extension of time to file the Second Amended Complaint (DE 13); Defendants filed its opposition brief five days later (DE 14); and Vicente filed his reply brief on February 9, 2021. (DE 15.) By order dated June 7, 2021, I granted Vicente's motion and ordered that the proposed Second Amended Complaint be filed within 60 days after the date of the order.

On August 6, 2021, Vicente filed the Second Amended Complaint against the Defendants. (DE 18.) Defendants moved to dismiss the Second Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) on August 19, 2021. (DE 19.) Vicente filed his opposition brief on September 7, 2021, and Defendants filed their reply brief three days later.

For the reasons set forth in this opinion, I will grant Defendants' motion to dismiss the Second Amended Complaint with prejudice.

II. Discussion

a. Legal standard

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. However, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 555 (2007); *see Philips v. Cnty. of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008) (Rule 8 "requires a 'showing' rather than a blanket assertion of an entitlement to relief.") (citation omitted). The Second Amended Complaint's factual allegation must be sufficient to raise Vicente's right to relief above a speculative level, so that a claim is "plausible on its face." *Twombly*, 550 U.S. at 570; *see also West Run Student Hous. Assocs., LLC v. Huntington Nat. Bank*, 712 F.3d 165, 169 (3d Cir. 2013).

Facial plausibility is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While this standard "is not akin to a 'probability requirement' … it asks for more than a sheer possibility." *Id.*

Further, Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim upon which relief can be granted. Defendants, as the moving party, bear the burden of demonstrating that no claim has been stated. *Animal Science Products, Inc. v. China Minmetals Corp.*, 654 F.3d 462, 469 n. 9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the Second Amended Complaint are accepted as true and all reasonable inferences are drawn in favor of Vicente. *New Jersey Carpenters & the Trustees Thereof v. Tishman Const. Corp. of New Jersey*, 760 F.3d 297, 302 (3d Cir. 2014).

b. New Jersey's Product Liability Act

As established in my prior opinion, the NJPLA "recognizes three claims: design defect, manufacturing defect, or failure to warn." *Mendez v. Shah*, 94 F. Supp. 3d 633, 637 (D.N.J. 2015). The NJPLA provides as follows:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J. Stat. Ann. § 2A:58C-2.

A product liability action is defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C-1(b)(3). Harm is defined to mean "(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph." N.J. Stat. Ann § 2A:58C-1(b)(2).

c. Implied warranty

As in their first motion to dismiss, Defendants argue that Vicente's claim for breach of implied warranty is subsumed by the NJPLA. (DE 19-1 at 5-6.) Defendants cite this Court's prior opinion stating that the NJPLA

> 'effectively creates an exclusive statutory cause of action for claims falling within its purview' and 'generally subsumes common law product liability claims, thus establishing itself as the sole basis of relief under New Jersey law available to consumers injured by a defective product.

(DE 11 at 9 (quoting *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991)). Because Vicente's harm stems from an allegedly "defective product," Defendants posit that the NJPLA governs the case and dictates that the Court dismiss the breach of implied warranty claim. (DE 19-1 at 5 (citing DE 11 at 10).)

In Count 4 of the Second Amended Complaint, Vicente realleges warranty claims: "[Defendants] expressly and implicitly warranted that the aforesaid products would be safe for insertion in patients' bodies," but the "products did not conform" to those warranties "in that their designs were flawed thereby posing a serious risk that the device could fail after surgery, and thereby giving rise to pain and suffering, debilitation, and the need for revision surgeries." (2AC ¶¶ 109-110). These allegations do not address the deficiencies I identified in my prior opinion. In that opinion, I held that Vicente's claim was essentially "one for personal injuries from a defective product," and therefore was subsumed by the NJPLA (DE 11 at 11 (citing *Hindermyer*, 419 F. Supp. 3d at 819).) Nothing about the Second Amended Complaint alters that analysis. I hold that Vicente's implied warranty claim is subsumed by the NJPLA because it alleges personal injuries from a defective product. *See Hindermyer*, 419 F. Supp. 3d at 819.

Vicente argues that Count 4 is not subsumed by the NJPLA because the Second Amended Complaint "contains numerous factual allegations of products used in plaintiff's surgeries for purposes which were later or even sometimes prior, re-labeled for different uses completely different from the original use." (DE 20 at 18.) Precedent dictates, however, that the Court go behind the labels and more searchingly "look at the essence of the claims and decide whether or not the plaintiff is disguising what would traditionally be considered a products liability claim as an alternative cause of action." *Hindermyer*, 419 F. Supp. 3d at 818 (internal quotation marks omitted) (quoting *New Hope Pipe Liners*, 2009 WL 4284611 at *2). Here, Vicente asserts that the aforesaid products did not conform to Defendants' express and implied

warranties "in that their *design was flawed*." (2AC ¶ 110) (emphasis added). As I held in my prior opinion, Vicente has merely repackaged a design defect claim as one for breach of implied warranty. (*See* DE 11 at 11.) His theory, if accepted, would obliterate distinctions between causes of action; any claim of a design flaw, for example, could be restated as a claim that the company, in marketing its product, impliedly represented that it did not have a design flaw.

Here, Vicente relies on the very same case law cited in his first opposition brief to argue "that representation-based claims are separate and distinguishable causes of action from the NJPLA." (*See* DE 20 at 19-22; DE 7 at 27.) My prior opinion discussed and distinguished those cases. It also noted that Vicente failed to allege any specific misleading representations or advertisements, but merely posited their existence as window dressing for his design defect claim. (DE 11 at 12-13 (citing Am. Compl. at ¶ 57).) Because the current Count 4 allegations are not appreciably different from their predecessors, the reasoning in my prior opinion is dispositive here.

Vicente's implied warranty claim must therefore again be dismissed.

d. Breach of Express Warranty

The NJPLA does, however, leave room for a claim of breach of express warranty. *See* N.J. Stat. Ann. §2A:58C-1(b)(3). As expressed in my prior opinion, an express warranty is established by the following:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J. Stat. Ann. § 12A:2-313(1). To properly plead a claim for breach of express warranty, Vicente "must properly allege: (1) that Defendant[s] made an

affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 706 (D.N.J. 2011).

Under New Jersey law, "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." N.J. Stat. Ann. § 12A:2-313(2). Courts in this District have dismissed express warranty claims where the pleading fails to allege factually the actual warranty-creating language. *Id.* at 707 ("Since Plaintiffs' allegations are simply 'bald assertions' that fail to identify specific affirmations or promises by Defendants, the claim as pleaded cannot survive a motion to dismiss.") *Simmons v. Stryker Corp.*, No. 08-3451, 2008 WL 4936982, at *2 (D.N.J. Nov. 17, 2008) ("Plaintiff's breach of warranty claim is devoid of any "factual matter" to support the existence of an express warranty. Rather, there is simply a conclusory recitation of the elements of the claim. Plaintiff has alleged no facts to suggest that an express warranty existed.") *Parker v. Howmedica Osteonics Corp.*, No. 07-2400, 2008 WL 141628, at *6 (D.N.J. Jan. 14, 2008) (general references to "press releases" and "assurances of safety," as opposed to specific statements, cannot survive a motion to dismiss).

The Second Amended Complaint—like the first—fails to identify the language or source of any alleged express warranty. Consequently, Vicente's express warranty claim must fail.

Vicente contends that the "names and descriptions of the products in the 'Specific Product Allegations' section of the second amended complaint sets forth numerous express warranties that were made in the names of the products and were subsequently found to be false." (DE 20 at 17.) I assume *arguendo* that the names and descriptions of the Defendants' devices could constitute an express warranty under New Jersey law. Nevertheless, the Second Amended Complaint fails to (1) allege that these descriptions formed

the basis of any bargain *with Vicente*; (2) specifically identify the product names or descriptions that *Vicente relied on* before undergoing the various procedures involving Defendants' devices; and (3) specifically allege which product, and in which respects, "did not conform to the affirmation, promise or description." *See Arlandson*, 792 F. Supp. 2d at 706.

That the Second Amended Complaint identifies other patients allegedly harmed by Defendants' devices is ultimately irrelevant to this analysis. Because Vicente has failed to adequately plead the elements of a breach of express warranty claim, I must dismiss the remainder of Count 4 of the Second Amended Complaint.

e. Design Defect

Under the NJPLA, the standard for liability "is that the product 'was not reasonably fit, suitable or safe for its intended purpose.'" *Mendez*, 94 F. Supp. 3d at 637 (quoting *Cornett v. Johnson & Johnson*, 998 A.2d 542, 562 (N.J. Super. Ct. App. Div. 2010)); *Hindermyer*, 419 F. Supp. 3d at 823 (quoting same). "The plaintiff must demonstrate that the 'product [was] manufactured as intended but the design render[ed] the product unsafe.'" *Sich v. Pfizer Pharm.*, No. 117-02828, 2017 WL 4407930, at *2 (D.N.J. Oct. 4, 2017) (alterations in original; quoting *Pollander v. Desimone BMW of Mt. Laurel, Ltd.*, No. A-3204-10T3, 2012 WL 127563, at *3 (N.J. Super. Ct. App. Div. Jan. 18, 2012))). A design defect claim has three essential elements: "(1) the product was defective; (2) the defect existed when the product left the hands of the defendant; and (3) the defect caused the injury to a reasonably foreseeable user.'" *Mendez*, 94 F. Supp. 3d at 637 (quoting *McGarvey v. G.I. Joe Septic Service, Inc.*, 679 A.2d 733, 740 (N.J. Super. Ct. App. Div. 1996)).

An actionable design defect may be alleged based on "the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm without substantially impairing the reasonably anticipated or intended function of the product." *Hindermyer*, 419 F. Supp. 3d at 823-24 (citing *Cavanagh v. Skil Corp.*, 751 A.2d 518, 520 (N.J.

2000)). Alternatively, a plaintiff may plead that "the product's risks outweighed its utility." *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 980 (N.J. 1998). Courts in this District have observed that during the pleading stage, while "there is no 'per se rule that Plaintiffs must, under all circumstances, provide a reasonable alternative design,' a plaintiff must plead either that the product's risk [of harm] outweighs its [utility], or that an alternate design exists, in order to state a claim for a design defect under the NJPLA." *Id.* (alteration in original (quoting *Mendez v. Shah*, 28 F. Supp. 3d 282, 297-98 (D.N.J. 2014) ["*Mendez I*"]).

Thus, Courts in this District have often dismissed design defect claims because the plaintiff failed to allege that a reasonable alternative design existed or that the risk outweighed the product's utility. *See, e.g., Hindermyer*, 419 F. Supp. 3d at 825 (dismissing a design defect claim because the plaintiff did not plead the existence of an alternative design); *Mendez I*, 28 F. Supp. 3d at 298 (dismissing a design defect claim because the plaintiff failed to present a risk-utility analysis); *Greisberg v. Boston Sci. Corp.*, No. 19-12646, 2020 WL 278648, at *5 (D.N.J. Jan. 17, 2020) (dismissing a design defect claim because the plaintiff did not provide either a risk-utility analysis or plead the existence of an alternative design); *Sich*, 2017 WL 4407930, at *2 (dismissing a design defect claim because the plaintiffs "simply alleged injury").

Vicente once again argues that he is not required to plead an alternative design or engage in a risk-utility analysis, because a design defect can be established through the "consumer expectations" test. (DE 20 at 6; *see also* DE 7 at 18.) And it is true that "[a] court may at times apply the consumer expectations test to determine whether a product was defectively designed." *McAlonan v. Tracy*, No. A-6034-07T2, 2011 WL 6125, at *6 (N.J. Super. Ct. App. Div. Mar. 16, 2010) (quoting *O'Brien v. Muskin Corp.*, 463 A.2d 298, 304 (N.J. 1983). The consumer expectations test, however, relies on common knowledge; it applies only when "it is *self-evident* that the product is not reasonably suitable and safe and fails to perform, contrary to the user's reasonable expectation that it would 'safely do the jobs for which it was built.'"

Id. (internal quotation marks omitted) (quoting *Suter v. San Angelo Foundry & Mach. Co*, 406 A.2d 140, 150 (N.J. 1979) (emphasis added).

A product design is "self-evidently" defective "when there are no relevant considerations which make the hazard inherent in the product or reasonably necessary to its functioning." *Mettinger*, 678 A.2d at 1123. In such circumstances, there is no need for a risk-utility analysis and "[t]he only material question is whether the product has been designed so as to pose a hazard that is contrary to the user's reasonable expectations." *Id.*

This, as Defendants argue, is not such a case; these products are complex and outside the experience of an ordinary consumer. (DE 21 at 3-4; *see also* DE 9 at 7-8.). Indeed, I have already held in my prior opinion that the consumer expectations test does not apply here:

> An average consumer would not know how long surgical screws maintain their structure after nonunion of a fracture. This is far from a lay person's common experience of, say, joining two pieces of wood with plates and screws. The system is not akin to the bicycle whose brakes do not hold, the hypothetical 'common knowledge' case ….

(DE 11 at 18.)

Vicente continues to argue that the alleged defects "are not complex because they involve the breaking of a plate and screws" (DE 20 at 6), I once again reject that argument as I did in my prior opinion. (DE 11 at 18.) There, I stated that the "soundness of the medical device at issue here is not within the ken of the average consumer," noting that the average consumer "would not know how long surgical screws maintain their structure after nonunion of a fracture." (DE 11 at 18.) Nor would the consumer be familiar with the avoidable or inevitable failure rate of such a medical procedure, the reducible or irreducible risks, and so on.

The Second Amended Complaint's allegations concerning other failures of devices manufactured by Defendants do not change that conclusion. Assuming as I must that the devices have failed in some instances, the complaint still fails to address how the design of these devices was self-evidently defective, or

rendered them unsafe for any foreseeable use. Broken bones must be treated; the design standard is not one of perfection, but reasonableness. And, as I previously remarked, a defect must be alleged factually; outside of the obvious, "consumer expectations" realm, "[i]t is not enough to allege that an injury should not have happened, so there must be a design defect." (DE 11 at 18.)

In the absence of plausible allegations of a reasonable alternative design or a risk-utility analysis, I must dismiss the design defect claim.

f. Manufacturing Defect

To establish a manufacturing defect claim, Vicente "must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, a reasonably foreseeable or intended user." *Myrlak v. Port Auth. of New York & New Jersey*, 723 A.2d 45, 52 (N.J. 1999). A defect exists "if a product 'deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." *Hindermyer*, 419 F. Supp. 2d at 824 (quoting N.J. Stat. Ann. § 2A:58C-1(a)). In determining whether a product contains a manufacturing defect, "the 'product may be measured against the same product as manufactured according to the manufacturer's standards.'" *Id.* (quoting *Mendez I*, 28 F. Supp. 3d at 298.)

At this, the pleading stage, Vicente need not set forth the nature or etiology of the defect with scientific precision. *Id.* Since evidence of a defect "in the manufacturing process is uniquely within the knowledge and control of the manufacturer, '[p]roof that a product is not fit for its intended purposes 'requires only proof … that 'something was wrong' with the product.'" (alterations in original) (quoting *Myrlak*, 723 A.2d at 52.) Nevertheless, "[t]he mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." *Myrlak*, 723 A.2d at 52.

Defendants argue that Vicente has again failed to plead facts supporting a manufacturing defect claim. (DE 19-1 at 8.) In my prior opinion, I found that he had failed to "identify the defect in the LC-DCP System that [Plaintiff's] doctor implanted" and "fail[ed] to allege any facts about the supposed manufacturing defect(s) that caused the device to fail." (DE 11 at 19 (citing DE 6-1 at 14).) Here, the Defendants submit that Vicente has again pled a boilerplate, conclusory allegation—that the Defendants' devices "were defective in their manufacturing when they left the hands of defendants' in that they deviated from product specifications." (DE 19-1 at 8 (citing DE 18 at ¶97.) The threshold for pleading supporting facts, for the reasons stated above, is not high, but the Second Amended Complaint fails to meet it.

Because of Vicente's repeated failure to identify, or even really suggest, *how* Defendants' devices deviated from their intended design, I must dismiss the manufacturing defect claim. *See, e.g., Dingler v. Am. Med. Sys., Inc.*, No. 19-18672, 2019 WL 6310057, at *2 (D.N.J. Nov. 25, 2019) (dismissing manufacturing defect claim because the plaintiff alleged only that the products "caused adverse reactions and did not perform their intended purposes" but did "not allege any standard—be it a design specification, formulae, or performance of the manufacturer, or an identical unit manufactured to the same manufacturing specifications or formulae—from which the Products deviated.")

As he did in relation to the design defect claim, Vicente again attempts to circumvent the usual requirements by resort to what amounts to an alternative test of obviousness or common knowledge. I find, however, that he has again failed to adequately plead the elements of that "intermediate product defect test":

> It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:

> (a) was of a kind that ordinarily occurs as a result of a product defect; and
>
> (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Myrlak, 723 A.2d at 55 (quoting *Restatement (Third) of Torts* § 3 (1997)).

Vicente argues that, under this formulation, he is relieved of the obligation to identify a particular manufacturing defect, because there is "sufficient circumstantial evidence" indicating "that the product was defective in its manufacture." (DE 20 at 11; DE 7 at 15.) According to Vicente, the severity and nature of his injuries, along with the immediacy of the injuries after surgery, adequately suggests "that something went wrong with the product." (DE 20 at 11.)

I am bound to assume the truth of allegations that Vicente and other patients suffered injury following the use of these devices. Still, the Second Amended Complaint is devoid of allegations supporting any inference that Vicente's injuries were (1) "of a kind that ordinarily occurs as a result of a product defect"; and (2) not "solely the result of causes other than product defect existing at the time of sale or distribution." *Myrlak*, 723 A.2d at 55 (quoting *Restatement (Third) of Torts* § 3 (1997)).[4]

As Vicente has not adequately pled the elements of the indeterminate product test, I find it inapplicable. Vicente's manufacturing defect claim is dismissed.

---

[4] Vicente mixes in claims made by Defendants concerning the reliability and safety of the at-issue devices which he says "turned out to be unfounded." (DE 20 at 11.) This allegation, more typical of a warranty claim, is not directly relevant to the elements of the indeterminate product defect test. I reject it here, as I did before. (DE 11 at 21 ("It appears Plaintiff is arguing that the product had a manufacturing defect because it deviated from Defendants' safety claims. Such contentions fall short, or perhaps somewhere to the side, of the intermediate product defect test."))

g. Failure to Warn

Under New Jersey law, manufacturers are "liable for harm caused by a failure to warn if the product does not contain an adequate warning or instruction." *Hindermyer*, 419 F. Supp. 3d at 824 (alteration in original) (internal quotation marks omitted) (quoting *Sich*, 2017 WL 4407930, at *3). The NJPLA defines an adequate warning as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." N.J. Stat. Ann. § 2A:58C-4. "A product warning or instruction that does not comport with this statutory requirement is defective." *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229, 1236 (N.J. Super. Ct. App. Div. 2006).

The Second Amended Complaint lacks allegations concerning the warning associated with the at-issue devices. Like the First Amended Complaint, the Second Amended Complaint states the following: "The aforesaid products surgically implanted in plaintiff's body were due to inadequate warning because the defendants' knew or should have known there existed a serious risk that the devices could fail after surgery, thereby giving rise to pain and suffering, debilitation, and the need for revision surgeries to replace the device[s], with the attendant risks of complications from such further surgery." (2AC at ¶ 103.) This conclusory allegation lacks the facts that would satisfy the minimal Rule 8 standards of pleading. *See Twombly*, 550 U.S. at 570.

Moreover, the NJPLA incorporates the "learned intermediary doctrine," by which a "pharmaceutical manufacturer generally fulfils its duty to warn the ultimate user of its prescription drug … when it supplies physicians with adequate information about a drug's dangerous propensities." *Banner*, 891 A.2d at 1236. Courts have recognized an exception to that doctrine "when a pharmaceutical company has advertised its drug directly to the consuming public." *Id.* (citing *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999). In dismissing the First Amended Complaint, I observed that it lacked any

allegations that "the assertions made by DePuy were directed at consumers" (DE 11 at 22.) The Second Amended Complaint contains no such allegations, either.

Finally, under the NJPLA, there is a rebuttable presumption that warnings or instructions approved by the FDA are adequate:

> If the warning or instruction given in connection with a drug or device or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate.

N.J. Stat. Ann. § 2A:58C-4. Absent evidence of deliberate concealment or nondisclosure of after-acquired knowledge of harmful effect, "compliance with FDA standards should be virtually dispositive of such claims." *Perez*, 734 A.2d at 1259. Vicente has not alleged any facts in the Second Amended Complaint that would rebut the presumption on either deliberate concealment or nondisclosure of harmful effects.

Accordingly, Vicente's failure-to-warn claim is dismissed.

III. Dismissal with Prejudice

The question remains as to whether I should dismiss the Second Amended Complaint with prejudice, or grant leave to file a third amended complaint. The Third Circuit has liberally permitted pleading amendments to ensure that "a particular claim will be decided on the merits rather than on technicalities." *Dole v. Arco Chern. Co.*, 921 F.2d 484, 487 (3d Cir. 1990). Where a complaint is dismissed on Rule 12(b)(6) grounds, "a District Court must permit a curative amendment, unless an amendment would be inequitable or futile." *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004) (emphasis added); accord *Philips v. Cty of Allegheny*, 515 F.3d 224, 236 (3d Cir. 2008) (citing *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002) (citing *Shane v. Fauver*, 213 F.3d 113, 116 (3d Cir. 2000)).

I have now twice dismissed Counts 1-4 for failure to state a claim under the NJPLA. The complaint has been amended twice, the first time in response to discussions between the parties' counsel, and a second time in response to this Court's opinion dismissing the First Amended Complaint. Vicente, given two opportunities, has failed to cure the deficiencies of the original complaint. The differences between the First and Second Amended complaints do not suggest that the plaintiff is progressing in the direction of an actionable claim. Accordingly, it appears that permitting him to amend for a third time would be futile.

This dismissal is therefore entered with prejudice, as a final decision of the Court.

IV. Conclusion

For the reasons set forth above, I will dismiss the Second Amended Complaint with prejudice. An appropriate order follows.

Dated: November 5, 2021

/s/ Kevin McNulty

Kevin McNulty
United States District Judge